PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Lixiao Wang**
Application No.:	**10/673528**
Filed:	**September 29, 2003**
For:	**Stent with Smooth Ends**
Examiner:	**William H. Matthews**
Group Art Unit:	**3774**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2N-6533-US04

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 1, 92-94, and 98-101 over Richter

In rejecting claims 1, 92-94, and 98-101 under § 102(e) over Richter (US 6,315,794), the Examiner asserts that Richter discloses "an expandable stent (fig 3A) comprising a coating of a drug . . . ." Applicant disagrees. Independent claim 1 recites, in-part, "a first biocompatible coating adhered directly on at least the metal outer surface of the first end portion of the main body portion, wherein the first biocompatible coating comprises a polymer or a drug contacting the metal outer surface . . . ."

Richter discloses a "multilayered metal stent." Title of Richter. In the embodiment of Richter referenced by the Examiner, Richter further discloses that the metal stent has a "[s]econd coating 202 [that] comprises a suitable radiopaque material such as gold, platinum, silver, and tantalum . . . ." Col. 4, ll. 65-66. The radiopaque material of Richter is not a "drug" or "polymer" as claimed.

The Examiner's assertion that the claimed term "drug" can be read to include the radiopaque coating (gold, platinum, silver, and tantalum) disclosed in Richter is erroneous. While the Examiner can properly assert the broadest reasonable interpretation of a term in light of the specification, the interpretation proposed in the Examiner is simply not reasonable. The Examiner essentially alleges that the specification has defined the term "drug" so broadly as to encompass

any and all materials. By the logic of the Examiner, a metal stent itself could be a drug in that it is used to "treat" a patient. This approach is unreasonable. One of ordinary skill in the art simply would not regard the radiopaque coatings of Ricther as "drugs."

The Examiner further asserts that paragraph [0050] of Applicant's Specification permits the claimed term "drug" to include radiopaque materials. Paragraph [0050] of the immediate Specification states, in-part, "[t]he coating 18 may also be used as a drug delivery system to prevent restenosis or for other treatment. The drugs may include radiochemicals to irradiate and prohibit tissue ingrowth." The Examiner asserts that the phrase "[o]ther treatment" may be considered "an imaging treatment or the mere expansion of the stent whereby the gold coating assists the delivery and expansion of the stent." The Examiner has misinterpreted this phrase. The Examiner uses the phrase "other treatment" as applying to the device. In other words, the Examiner appears to consider the "other treatment" to include "an imaging treatment" or a treatment of gold coating that "assists the delivery and expansion of the stent." The radiopaque coatings of Richter are merely used to view the device during fluoroscopic procedures. In contrast, the "treatment" discussed in Applicant's Specification with respect to the claimed "drug" is used to refer to the treatment of the patient. Therefore, the Examiner's reliance on the phrase "or other treatment" is misplaced. One of ordinary skill in the art would not characterize the radiopaque coatings of Richter as "drugs." *See e.g.*, MPEP § 2111.01 (words of a claim must be given their plan meaning – "the meaning that the term would have to a person of ordinary skill in the art . . . .") (internal citations omitted). The term "drug" is not so broad as to encompass a radiopaque coating added to a stent.

At least in light of the foregoing, the Examiner's assertion that the radiopaque materials of Richter can be considered "drugs" is erroneous and Applicant requests withdrawal of the rejection of independent claim 1 and dependent claims 92-94 and 98-101.

Claims 1, 91, 92, 94, and 98-101 over Kranz

In rejecting these claims over Kranz (US 6,312,456) under § 102, the Examiner asserts, "[t]he coating 4 [of Kranz] comprises a metallic material which is encompassed by the broadly claimed "drug", and in view of the broad definition afforded the term in the specification at paragraph [0050] of the published application (note line 2 "or for other treatments" and the final line)." Page 5. Applicant disagrees.

Kranz discloses a "biocompatible stent with radiopaque markers." Title of Kranz. Kranz further indicates that gold and silver can be used as X-ray opaque materials. Col. 3, ll. 32-34.

The Examiner's assertion that the radiopaque materials of Kranz are properly characterized as Applicant's claimed drugs or polymers is erroneous. As discussed above with respect to Richter, the skilled artisan would not regard "drugs" or "polymers" as radiopaque markers. Consequently, the Examiner's rejection of claims 1, 91, 92, 94, and 98-101 over Kranz is *traversed* and Applicant requests withdrawal of the rejection.

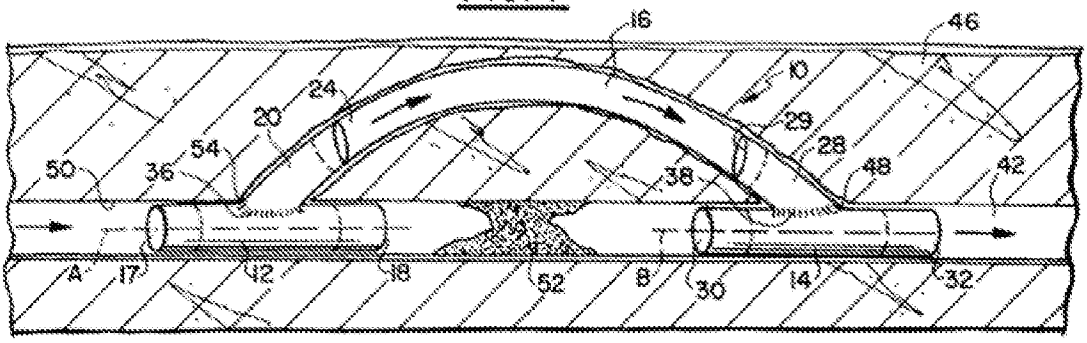
Claims 1, 91, 95, 100, 101, 108-110, 114, 119, and 120 over Venbrux

The Examiner rejected claims 1, 91, 95, 100, 101, 108-110, 114, 119, 120, under § 102 over Venbrux (US 5,443,497). Claim 1 is illustrative, and recites, in-part:

> a first biocompatible coating adhered directly on at least the metal outer surface of the first end portion of the main body portion, . . . and wherein the metal outer surface and the metal inner surface of the middle portion are free of the polymer or drug.

In rejecting the above referenced claims over Venbrux, FIG. 1 of which is shown below, on pages 2-3, the Examiner asserts, "stent 12 may be considered to comprise first end portion 20 having a coating and ePTFE tube 16 sewn thereto, middle portion 18, and second end portion 17. . . ."

FIG. 1



The Examiner's assertion that the "outlet 18" of Venbrux can be referred to as Applicant's claimed "middle portion," is erroneous. MPEP § 2111.01 requires that the words of a claim be given their 'plain meaning' unless it is inconsistent with the specification. Moreover, the plain meaning is that given by one of ordinary skill in the art. *Id.* One of ordinary skill in the art would not interpret the "outlet 18" of Venbrux to be Applicant's claimed "middle portion."

The Examiner's assertion that the "outlet 18" of Venbrux can be referred to as the claimed "middle portion," is not supported by disclosure of Venbrux, the plain meaning of the term, or Applicant's Specification. Instead, the "outlet 18" of Venbrux is disposed at an end of the proximal stent 12, not on a "middle portion."

Consequently, Venbrux does not disclose what is claimed in independent 1, 91, 95, 100, 101, 108-110, 114, 119, 120, and Applicant requests withdrawal of the rejections thereof.

Claims 1, 91, 92, 94, 96-100, 108-111, 113, and 115-119 over Scott and Myers

The rejection of these claims over Scott (US 5,383,928) and Myers (US 5,700,285) under 35 USC § 103(a) is *traversed*.

Scott teaches away from using a "coating." Scott proposes using a "separate sleeve to encompass the stent . . . ." Col. 4, l. 12. The sleeve of Scott is proposed to overcome certain deficiencies of coatings on stents. The Examiner nonetheless asserts that "a sleeve meets the broadest reasonable interpretation of a coating as claimed," because "[a] coating is defined as a material covering a substrate." Final Office Action at 3.

Applicant disagrees. The Examiner's definition of a "coating" is overly broad and the Examiner has cited no precedent for the "definition" proposed. Indeed, although the Examiner attempts to shoehorn the "sleeve" of Scott into the definition of coating by providing an overly broad definition of "coating," as noted above, Scott distinguishes between a sleeve and a coating. *See e.g.*, col. 4, ll. 1-14.

Myers does not cure these deficiencies of Scott. Consequently, the Examiner has failed to establish a *prima facie* case of obviousness and Applicant requests withdrawal of the rejection of claims 1, 91, 92, 94, 96-100, 108-111, 113, and 115-119 over Scott and Myers.

Claims 1, 91-101, and 105-123 over Berg, Scott, Nolting, and Jang

The rejection of claims 1, 91-101, and 105-123 over Berg (US 5,464,650) in view of Scott (US 5,383,928), Nolting (US 6,488,701), and Jang (US Pub. No. 2004/0106985) under 35 USC § 103(a) is *traversed*.

The Examiner has mischaracterized the disclosure of Scott. The Examiner's assertion that "Scott teaches the discovery that localized delivery of a drug requires less drug and imparts less systemic delivery of the drug," is overly broad. As indicated above, Scott discloses, "a separate sleeve . . . ." Col. 4, l. 12. In addition, the Examiner has provided no support for the

assertion that "[t]he coating of Berg is improved and is flexible to expand with the stent . . . ." And, for the sake of argument only, even if the device of Berg is "improved," the Examiner has not shown that the "improved" coating of Berg does not suffer from certain problems identified in the Background section of the Scott patent. Consequently, the Examiner has failed to provide support for the purported motivation to modify the device of Scott with the teachings of Berg.

Furthermore, a person having ordinary skill in the art would not modify the stent of Berg in light of Nolting in a way that would satisfy the recited claim language. Nolting discloses a "stent (60), a first thin membrane (62) defining a luminal surface, a second thin membrane (64) defining a vascular surface and a coating (65)." Col. 10, ll. 1-4. Modifying the stent of Berg with the disclosure of Nolting would not produce a stent wherein the metal outer surface and the metal inner surface of the middle portion are free of any coating comprising a polymer or a drug. Indeed, neither Nolting nor Berg discloses this claimed subject matter.

Modifying Berg with the disclosure of Nolting would be expected to produce a stent largely in accordance with the disclosure of Nolting. Specifically, the thin membrane (64) of Nolting extends the entire length of the stent. The coating 65 appears to be disposed over the thin membrane 64. Thus, it is not disposed "directly on" the stent, as is claimed.

For at least the foregoing reasons, the Examiner has failed to establish a *prima facie* case of obviousness and Applicant requests withdrawal of the rejections over Berg, Scott, Nolting, and Jang.

Respectfully submitted,

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